UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY

UNITED STATES OF AMERICA ex rel. ROBERT A. LITER	)	**Civil Action No. 06-176-WOB**
	)	
	)	**FILED IN CAMERA AND UNDER SEAL**
Plaintiff,	)	
	)	
v.	)	
	)	**FIRST AMENDED COMPLAINT**
PFIZER, INC.	)	
	)	**TRIAL BY JURY REQUESTED**
Defendant.	)	

I. INTRODUCTION

1. This is an action brought by Robert A. Liter on behalf the United States of America, to recover damages and civil penalties arising from the actions of Pfizer, Inc. who is regulated by the United States Food and Drug Administration, and who is alleged to have illegally pursued and secured payment for the purchase of its drug Pregabalin from the United States, through the Veteran's Administration, Federal Employees Health Benefits Program, Medicare and Medicaid Corporations, and who is being alleged to have retaliated against Robert A. Liter all in violation of the federal False Claims Act, 31 U.S.C §3729 et seq., and pursuant to analogous provisions of state law.

2. The False Claims Act was intended by Congress to create incentives for individuals aware of fraud against the Government to disclose information without fear of reprisals or Government inaction.

3. The False Claims Act allows any person having knowledge of a fraud or fraudulent claim against the Government to share in any recovery. The complaint was filed under seal (without service on the Defendants during the same period) to enable the United States

Government (1) to conduct its own investigation without the knowledge of the Defendants, and (2) to determine whether to join the suit. The Plaintiff has also filed, with the Attorney General of the United States, a detailed statement disclosing all material evidence and information in Plaintiff's possession.

4. Plaintiff seeks to recover damages and civil penalties from Pfizer, Inc. for its fraudulent use of Government funds. Plaintiff further seeks to recover damages from Pfizer, Inc. for its retaliatory conduct against Plaintiff.

5. As required by the False Claims Act, 31. U.S.C. §3730 (b)(2), Plaintiff has provided to the Attorney General of the United States through the United States Attorney General of Kentucky, simultaneously with the filing of this Complaint, a Disclosure Statement of all material evidence and information related to the Complaint. This Disclosure Statement is supported by documentary evidence establishing the existence of false or fraudulent claims presented by or caused to be presented by Defendant to the United States government for payment. It is labeled "Disclosure Statement".

II. PARTIES

6. Plaintiff and Relator, Robert A. Liter (hereinafter "Relator"), resides at 2003 Indigo Drive, Richmond, Kentucky, 40475. Relator was employed by Defendant Pfizer as a Professional Healthcare Representative from July 7, 1999 through August 30, 2006, when Relator was involuntarily terminated. Relator is the original source of the facts and information hereinafter set forth concerning the activities of Defendant Pfizer. The facts averred herein are based entirely upon his personal observation and documents in his possession. Relator has a B.A. Degree from Hanover College, and has previously received an honorable discharge from the U.S. Army, where he served for six years.

7. Defendant Pfizer, Inc. (hereinafter "Pfizer") is a Delaware Corporation with its principal place of business in New York, New York. Pfizer is principally engaged in the manufacture and sale of pharmaceuticals, including prescription pharmaceuticals falling under the jurisdiction and regulation of the Food and Drug Administration (hereinafter "FDA"), throughout the Commonwealth of Kentucky and the United States. Pfizer is licensed to market pharmaceuticals in the Commonwealth of Kentucky.

III. JURISDICTION AND VENUE

8. This is a civil action arising under the laws of the United States to redress a violation of 31 U.S.C. §3729 and 31 U.S.C. §3730, also know as the "False Claims Act."

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and 31 U.S.C. §3732, which specifically bestow jurisdiction on this Court for actions brought pursuant to §3729 and §3730 of Title 31of the United States Code.

10. This Court has personal jurisdiction over Pfizer because Pfizer has established operations in the Eastern District of Kentucky, and thus transacts business within the District and events described herein transpired within this District.

11. Venue is proper in this District pursuant to 31 U.S.C. §3732(a), because Pfizer is licensed to conduct business and can be found to transact business in the Eastern District of Kentucky, and the events described herein transpired within the Eastern District of Kentucky.

IV. BACKGROUND

12. As will be more fully set out below and in Relator's Disclosure Statement, this is primarily a claim for damages under the False Claims Act regarding Pfizer's illegal promotion and sale of the prescription drug Pregabalin, brand-name Lyrica. Pfizer has a responsibility to Plaintiff, United States, to properly charge and have charged the federal programs and agencies,

including but not limited to Medicare, Medicaid and the Department of Veterans Affairs, which directly or indirectly pay for the drugs manufactured, marketed and sold by Pfizer.

13. Pfizer, which manufactures, markets and sells the prescription drug Lyrica, has sold and is selling significant quantities of Lyrica to Veterans Health Administration facilities, and indirectly, via targeted physicians, to patients whose prescriptions are paid for in whole or in part by state administered medical assistance programs which receive up to 90% reimbursement from federal programs, i.e. Medicare and Medicaid.

14. A drug manufacturer is required by The Federal Food, Drug, and Cosmetic Act to specify the intended use or uses of a product in its new drug application to the FDA. Once a drug is approved for its intended use, as set out in the new drug application, the Federal Food, Drug and Cosmetic Act places restrictions on how a drug may be marketed or promoted.

15. The Federal Food, Drug, and Cosmetic Act prohibits a manufacturer from marketing or promoting the drug for any use that was not specified in the new drug application and approved by the FDA. Uses of a prescription drug for purposes other than those approved by the FDA are referred to as "off-label" uses.

16. It is further a violation of the Federal Food, Drug and Cosmetic Act for a manufacturer to market or promote a drug through the dissemination of false or misleading information. Information is deemed false or misleading if it contains an unapproved representation or suggestion that the drug is safer or more effective than has been demonstrated by substantial evidence or substantial clinical experience. 21 C.F.R. 202(e)(6)(i). A comparison that suggests that a drug is safer or more effective than another drug is unlawful if it has not been demonstrated to be safer or more effective by substantial evidence or substantial clinical experience. 21 C.F.R. 202(e)(6)(ii).

17. In violation of federal law and for the intended purpose receiving payments, either directly or indirectly from the United States, Pfizer knowingly and deliberately promoted Lyrica illegally for off-label uses and through the dissemination of misleading information.

18. Through the unlawful promotion of Lyrica, as briefly set forth above, Pfizer has received and is continuing to receive significant payments, both directly, through the sale of Lyrica to VA Hospitals, and indirectly, through distributors of Lyrica who are reimbursed by federal programs such as Medicare and Medicaid, from the United States.

19. Relator reported his concerns to Pfizer regarding the unlawful promotion of Lyrica. After reporting his concerns to Pfizer regarding the unlawful promotion of Lyrica and in retaliation for reporting his concerns regarding the unlawful promotion of Lyrica, Relator was placed on administrative leave and subsequently terminated.

V. FACTUAL ALLEGATIONS

20. The Relator has prepared and will serve with this Complaint, a Disclosure Statement pursuant to 31 U.S.C. § 3730(2) of information in his possession and of which he is the original source. Such information substantiates that Pfizer, by its repeated actions, knowingly and willfully breached its legal obligations to the United States Government, including but not limited to its obligation to abide by federally mandated FDA rules. Such violations are continuing.

A. LYRICA APPROVED BY FDA FOR LIMITED USES

21. On December 30, 2004, Pfizer obtained approval from the FDA to market the prescription drug, Pregabalin for specific and limited uses. Specifically, the FDA approved Pregabalin for use in the treatment of diabetic peripheral neuropathy and postherpetic neuralgia. On June 13, 2005, the FDA approved Pfizer to market Pregabalin for the additional use of

adjunctive treatment of partial onset seizures in adults with epilepsy. Doses for the FDA approved uses of Pregabalin are 50 mg/d to 600 mg/d. Pfizer thereafter began to market and promote the drug Pregabalin under the brand name LYRICA.

22. As of Relator's termination from employment with Pfizer on August 30, 2006, the FDA had not approved the use of Lyrica for any other indication or in any other dosage. The FDA approved use of Lyrica represents a relatively narrow market, since it includes only persons suffering from three indications described above.

23. Lyrica, according to the clinical trials presented to the FDA by Pfizer, is a controlled substance and has been given a schedule V by the FDA as "potentially addictive". Because of its controlled substance status and addictive properties, Lyrica must have prescriptions written on a physician's green prescription pad, and is, as all controlled substances, strictly monitored by the D.E.A.

B. PFIZER FORMED A SCHEME TO ILLEGALLY PROMOTE LYRICA

24. After achieving FDA approval of Lyrica, Pfizer formed a scheme to maximize the sales of Lyrica. The overall scheme developed by Pfizer included the promotion of Lyrica for off-label uses and the promotion of Lyrica through unsubstantiated comparative studies concerning the efficacy of Lyrica versus other drugs that were then available.

25. As noted above, once Lyrica was approved by the FDA for certain specific uses, Pfizer was prohibited by the Federal Food, Drug, and Cosmetic Act from marketing or promoting Lyrica for any off-label uses. It is further unlawful to market or promote a drug through the dissemination of false or misleading information, including unsubstantiated information regarding the safety and effectiveness of a drug.

26. Pfizer knows and has known about the restrictions regarding the promotion and marketing of drugs. In fact, in 2004, Pfizer paid $430 million as a result of a guilty plea in a similar case involving the fraudulent promotion of Neurontin. As is the case with Lyrica in the present case, Neurontin was aggressively marketed for the treatment of off-label uses.

27. In addition to knowing the regulations with regard to the marketing or promoting of a drug, Pfizer further knew or reasonably should have known that the unlawful promotion of Lyrica would either result in the sale of Lyrica directly to the federal government or would result in a sale of Lyrica that would be reimbursed by the federal government. Pfizer has sales representatives that are responsible for selling directly to government funded facilities such as VA Hospitals. Furthermore, Relator promoted Lyrica to doctors who have a large percentage of patients whose prescriptions are largely paid for by government assistance programs such as Medicare and Medicaid.

28. The unlawful promotion of Lyrica was developed as a way to dramatically and rapidly increase the sale of Lyrica. By promoting Lyrica for off-label uses, Pfizer could expand the market for Lyrica, without the substantial expense and delay of petitioning the FDA for approval of expanded or additional uses. By promoting Lyrica through the dissemination of unsubstantiated studies/reports, Pfizer could convert the users of competing drugs to Lyrica.

C. PFIZER INSTRUCTED REPS TO ILLEGALLY PROMOTE LYRICA

29. Despite the fact that Pfizer knew that it was illegal to market or promote Lyrica for off-label uses and through the dissemination of misleading information, Pfizer, through its management level employees, provided instruction and guidance to its sales representatives, including Relator, encouraging them to illegally promote Lyrica. The sales representatives, including Relator were specifically instructed to promote Lyrica for the following off-label uses:

pain control, bipolar disorder, fibromyalgia syndrome, back pain, generalized anxiety disorder, post surgical pain, social anxiety disorder, migraine headache, multiple sclerosis, acute dental pain, pain due to spinal cord injury, thalmatic pain syndrome, and many more diseases and conditions. The sales representatives were further provided unapproved studies comparing the efficacy of Lyrica with Neurontin (gabapentin), Cymbalta, Keppra and several other drugs and encouraged sales representatives to utilize those studies to promote the sale of Lyrica.

30. Pfizer sales representatives are rated and paid and receive incentives based on their sales ranking under a rating scale called the GAR. All sales representatives are pushed to follow Company promotional training to increase their sales, and to follow the direction of their Regional and District Sales Managers. Relator and other sales representatives were told that, as part of good sales activities, they should promote Lyrica for off-label uses and through the dissemination of information in unsubstantiated studies which compare Lyrica to other drugs.

31. Beginning in September, 2005, and continuing through October and November, Pfizer held a series of "launch meetings" for the purpose of promoting the sale of Lyrica. The purpose of such "launch meetings" is to inform the sales representatives of the product details, to give guidance in the sale and marketing of the product and to discuss the sales goals for the particular product.

32. During the week of September 16-22, 2005, Pfizer held a National Sales Meeting in Anaheim, California, to launch the sale of Lyrica. At the National Sales Meeting, Relator and the other sales representatives in attendance received instruction and guidance from Pfizer senior sales executives on ways to promote the sale of Lyrica. Among the instruction and guidance provided to the sales representatives, Pfizer instructed and encouraged Relator and the other sales representatives to employ the following illegal promotional tactics to promote the sale of Lyrica:

a. Direct solicitation of physicians to prescribe Lyrica for "off-label" uses.

b. Use of unsubstantiated scientific reports and comparative studies to promote the sale of Lyrica, including but not limited to the sale of Lyrica for "off-label" uses.

c. Making false statements to physicians and pharmacists concerning the efficacy and safety of Lyrica for "off-label" uses.

d. Direct solicitation of physicians to promote the sale of Lyrica for "off-label" uses.

e. Deliberately defying the FDA's classification of Lyrica as to its therapeutic equivalency and thus the avoidance of Medicare and Medicaid price limitations based on therapeutic equivalency.

f. Actively concealing its promotional scheme from the FDA to avoid that agency's enforcement mechanisms and to thus avoid the FDA's resultant mandatory interruption of Medicare and Medicaid payments for Lyrica prescriptions.

g. Actively concealing its promotional scheme from the "formulary" policies of various state agencies administering Medicare and Medicaid programs which are intended to refuse payment for uses of drugs which are not medically recognized as statutorily defined.

h. Concealing its sales and promotional tactics for "off-label" uses of this controlled substance Lyrica from the DEA and other investigatory authorities.

33. During the National Sales Meeting, a series of District Breakout Meetings were held for those sales representatives within each sales district. During the District Breakout Meeting attended by Relator, Regional Manager, Steve Reese, expressed a sense of urgency in launching sales of Lyrica. Mr. Reese specifically encouraged sales representatives to promote the sale of Lyrica for off-label uses through the use of "medical inquiries." A "medical inquiry" is a request from a doctor for information about a drug to help that doctor determine whether or not a drug will be effective for a specific patient or a specific treatment. Pfizer, through Mr. Reese and others, advocated the submission of medical inquiries, regarding the efficacy of

Lyrica for off-label uses and comparing Lyrica to other drugs, on behalf of doctors or healthcare providers, to encourage a doctor or healthcare provider to prescribe or purchase Lyrica. During a District Breakout Meeting, Relator vocalized his concerns in front of everyone in attendance about submitting unsolicited medical inquiries regarding off-label uses on behalf of physicians. In response to these vocalized concerns, Mr. Reese addressed every member of the district sales team, and said "I'm telling you to send as many medical inquiries as you can", and if you "get any calls or heat from the medical inquiry desk", send them on to me and "I'll take the heat for you!"

34. On Thursday, September 22, 2005, Relator received an e-mail from his immediate supervisor and District Manager, Clay Fuller, with an attachment called a "Lyrica Launch Tracker". The "launch tracker" that was sent to Relator and other members of the district sales team encouraged sales representatives to submit medical inquiries regarding Lyrica.

35. On Saturday, September 24, 2005, Clay Fuller sent a follow-up email to Relator and other members of his district sales team further encouraging sales representatives to use the Lyrica Launch Tracker and informing the sales representatives that he would be reviewing individual Launch Trackers on upcoming "field rides".

36. In addition to generally encouraging the use of the Launch Tracker, including the use of "medical inquiries", Mr. Fuller instituted a "sales contest" in which the sales representative who had completed the most activities on the Lyrica Launch Tracker would receive "ace points." Ace points are the equivalent to cash vouchers that can be used to purchase gift cards, sports equipment, etc. from the Ace point catalog.

37. Mr. Fuller further instituted a sales contest which gave ace points to the sales representative who had the most of their "top 40 physicians" write a sample Lyrica prescriptions

on green index cards. The contest was instituted to further promote Lyrica to doctors and to get the doctors comfortable writing the prescription on a green controlled substance prescription pad.

38. On Friday, September 23, 2005, Relator received an e-mail that was generated by Richard Vissing, Director, Regional Medical & Research and forwarded by Steve Reese, Regional Manager for the Indiana/Kentucky Sales Region, which included a list of "Medical Information Letters" for Lyrica. Medical Information Letters are unauthorized studies regarding the effectiveness of a drug for treating certain symptoms, often comparing the drugs effectiveness versus another drug. Upon receipt of these letters, Relator understood that the "Medical Information Letters" and information contained therein was to be utilized to promote the sale of Lyrica.

39. Following the e-mail that Relator received on September 23, 2005, Relator received a hard copy of a list entitled "MDI Pregabalin October 2005. This document provided a more expansive list of articles that existed addressing the effectiveness of Lyrica for off-label uses and comparing Lyrica with other drugs. Upon receiving the list, Relator interpreted that he was authorized if not required to utilize this information to promote the sale of Lyrica.

40. From October 31, 2005 – November 2, 2005, Relator attended a Point-Of-Action (POA) Meeting held in Indianapolis, Indiana. On November 1, 2005, at the POA meeting with over eighty (80) other Pfizer sales representatives and district managers, including Mark Beauchamp, Tony Barry and Jill Phelps, the Regional Sales Manager for Indiana and Kentucky, Steve Reese, urged all sales representatives who were present to "send as many medical inquiries" as possible on Lyrica.

41. Pfizer further distributed lists of physicians that were familiar with Lyrica to sales representatives and instructed the sales representatives to employ these physicians to promote the

use of Lyrica for both approved and unapproved uses. These physicians, referred to by Pfizer as Key Opinion Leaders, are compensated to speak regarding the efficacy of Lyrica at elaborate presentations attended by other physicians. Key Opinion Leaders are compensated to promote the efficacy of Lyrica for approved and unapproved uses. Key Opinion Leaders promote the efficacy of Lyrica for off-label uses by either presenting on off-label uses directly or by responding to sales representatives or other physicians that are "planted" in the crowd for the express purpose initiating a discussion about off-label uses for Lyrica.

D. PFIZER REPS ILLEGALLY PROMOTED LYRICA

42. Pursuant to the instruction and pressure received from sales executives of Pfizer and in reliance thereon, Relator and other sales representatives promoted Lyrica as instructed.

43. Upon receiving a list of "off-label" and non-approved FDA indications for Lyrica, Relator submitted requests, on behalf of his physicians, for medical inquiries depending upon the specialty of the particular physician. Relator would typically request a medical inquiry for his physicians once a week over a period of approximately three weeks. A list of physicians that Relator called on and requested medical inquiries on behalf of is provided in Relator's Disclosure Statement.

44. During the wee week of October 18, 2005, Relator submitted 47 medical inquiries on behalf of his physicians. On Tuesday, October 25, 2005, Pfizer Medical Information Manager, Yuan Wang forwarded an e-mail to Clay Fuller, identifying concerns regarding the "nature and origin of the medical information requests" submitted by Relator during the week of October 18, 2005. Although the medical inquiries regarding off-label uses were a direct result of the off-label promotional efforts of Relator, per the instruction he had received from management employees, Clay Fuller responded to Yuan Wang by e-mail and without conferring

with Relator that, "Bob Liter has submitted his medical inquiry request on an appropriate and unsolicited basis."

45. In April, 2006, Jill Phelps, the Therapeutic Specialty sales representative, whose target market was the Veteran's Administration Hospital and other government provider hospitals informed Relator that she had also solicited a large number of "medical inquiries" for that same time period, and that she had been copied on a similar letter from the Medical Inquiry department, questioning the legitimacy of the medical inquiries that had she had submitted.

46. On multiple occasions and per the instruction and guidance of Pfizer, Relator employed Key Opinion Leaders to promote Lyrica, including the promotion of Lyrica for off-label uses, at presentations for other doctors. See Disclosure Statement for details.

E. UNITED STATES PAID FOR FRAUDULENT SALES OF LYRICA

47. Through the unlawful promotion scheme that was developed and monitored by Pfizer and carried out by the sales representatives of Pfizer, including but not limited to Relator, Pfizer sold a significant amount of of Lyrica which was purchased by the United States either directly, through facilities operated by the Department of Veterans Affairs or similar government operated facilities, or indirectly, through the sale of Lyrica through physicians whose patients' prescriptions were paid largely through government programs such as Medicare and Medicaid.

48. For the sales year beginning September 1, 2005, Relator ranked in the top 5 for Lyrica sales. Relator has every reason to believe this high volume of sales was due in large part to his efforts to promote the sale of Lyrica, including the medical inquiries he requested on behalf of the majority of his physicians regarding Lyrica. Relator further has reason to believe that the prescriptions purchased by patients of his physicians were reimbursed by government programs such as Medicare and Medicaid.

49. Jill Phelps, the Therapeutic Specialty sales representative, whose target market was the Veteran's Administration Hospital and other government provider hospitals, confirmed in a conversation with Relator in April, 2006 that she solicited medical inquiries on behalf of her clients. In light of Ms. Phelps' target market, it is reasonable to believe that Lyrica was purchased directly by the federal government.

F. RETALIATION AGAINST PLAINTIFF/RELATOR

50. Prior to April, 2006, Relator had experienced a great deal of success in his six (6) year career with Pfizer and had consistently received positive performance reviews.

51. Following the April, 2006 conversation with Jill Phelps that is mentioned above and in which Relator expressed his concerns regarding the solicitation of medical inquiries, Relator noticed a change in the way he was being treated by his direct supervisor, Clay Fuller. In the above referenced conversation, Relator informed Jill Phelps, a friend of District Manager, Clay Fuller, of his intention to discuss his concerns regarding medical inquiries with Pfizer Corporate Compliance.

52. As more fully set out in Relator's Disclosure Statement, Relator began to notice a change in the way that he was being treated by management employees shortly after the above referenced conversation with Jill Phelps in April, 2006. The ratings that Relator received from Clay Fuller began to sharply decline. Relator noticed a marked change in the way that Mr. Fuller was treating him on April 19, 2006, during a "field ride".

53. On May 12, 2006, Relator anonymously contacted Pfizer Corporate Compliance hotline and filed a complaint regarding his concerns about using unsolicited medical inquiries as a mass marketing tool. Relator was assured that Pfizer has a "no retaliation" policy for individuals coming forward and reporting on any matter with regard to corporate compliance.

When Relator called the corporate hotline to check the status of his complaint on May 17, 2006, Relator was informed that his complaint had been forwarded to Pfizer.

54. On May 24, 2006, Relator, in reliance on Pfizer's well-publicized "no retaliation" policy, called the Corporate Compliance hotline, provided his name and expressed his concerns regarding the use of unsolicited medical inquiries as a mass marketing tool. During this call, Relator was asked to mail a copy of the Lyrica Launch Tracker spreadsheet to Global Compliance Services, Attn: Alert Line, 13950 Ballantyne Corp. Pl., Suite 300, Charlotte, NC 28277.

55. During the first week of June, 2006, Lisa Shrayer, Pfizer Corporate Counsel, contacted Relator and scheduled a meeting for Monday, June 12, 2006 at 2:30 p.m. at Griffin Gate Marriott Resort & Spa in Lexington, Kentucky to further discuss his concerns regarding the promotion of Lyrica. On June 12, 2006, Relator met with Lisa Shrayer and Martine M. Beamon and Ross B. Galin of the law firm Davis, Polk & Wardell. During this meeting Relator provided these individuals copies of the Lyrica Launch Tracker, e-mails with Medical Information letters and unapproved FDA indications for Lyrica. Relator further expressed concerns of being retaliated against during this meeting. Relator was assured that he would not be retaliated against.

56. During the June/July, 2006 time period, Relator had several other conversations with Lisa Shrayer. Relator expressed his concerns regarding retaliation on multiple occasions. Each time Relator expressed his concerns, he was informed that he was doing the "right thing" by reporting his compliance concerns and assured that he would not be retaliated against.

57. In July or August of 2006, Elaine Keating, Regional Director for Pfizer Human Resources scheduled a meeting for Monday, August 28, 2006 in Cleveland, Ohio to be attended

by Relator, Ms. Keating, Steve Reese, and Clay Fuller to address his Human Resources concerns.

58. On August 23, 2006, prior to the previously scheduled meeting in Cleveland, Ohio, Relator attended a meeting at Pfizer Corporate Headquarters in New York with Lisa Shrayer, Martine M. Beamon and Ross B. Galvin. Relator was told the meeting was to assist him in separating Human Resource issues from corporate compliance issues at the upcoming meeting in Cleveland scheduled by Elaine Keating. During this meeting, Lisa Shrayer informed Relator that effective immediately he was being placed on administrative leave.

59. On August 30, 2006 at 10:30 a.m., while still on administrative leave, Elaine Keating, Regional Human Resource Director and Amy Jenner, area Vice President of Sales and Steve Reese's immediate supervisor called Relator, and Ms. Jenner stated, due to extenuating circumstances, based on Relator's meeting with corporate compliance on August 23, 2006 and Relator's lack of integrity", that Relator was being terminated as a Pfizer employee.

VI. CAUSES OF ACTION

COUNT ONE
False Claims Act, 31 U.S.C. §3729 (a)(1)

60. Relator realleges and incorporates by reference herein each and every allegation made above in paragraphs 1 through 59 of his Complaint as part of his claim for damages and forfeitures under the False Claims Act, 31 U.S.C. §§3729-3732.

61. All of the conduct referred to above, regarding the promotion of Lyrica in violation of FDA rules, payment of illegal promotions to physicians, deliberate avoidance of federal price controls of experimental drugs and drugs with therapeutic equivalents, inducement of physicians and the Department of Veterans Affairs to prescribe or purchase Lyrica by use of false

statements, and avoidance of state formulary restrictions, are substantial and deliberate frustrations of clear federal law, regulation, and policy concerning the promotion and sale of prescription drugs

62. Pfizer's false or fraudulent claims regarding the efficacy of Lyrica made or caused to be made to doctors or to officers, employees, and/or agents of the United States for the purpose of having false or fraudulent claims paid by the United States, constitute false or fraudulent claims for payment or approval in violation of 31 U.S.C. §3729 (a)(1).

63. Plaintiff, United States, unaware of the falsity of the records, statements and/or claims made or used, or caused to be made or presented by Pfizer, and in reliance of the accuracy thereof, paid Pfizer as reimbursement for the use of Pregabalin/LYRICA in Kentucky and across the United States.

64. By reasons of these payments, the United States has been damaged in substantial amounts.

COUNT TWO
False Claims Act, 31 U.S.C. §3729 (a)(2)

65. Relator realleges and incorporates by reference herein each and every allegation made above in paragraphs 1 through 64 of this Complaint as his claim for damages and forfeitures under the False Claims Act, 31 U.S.C. §§3729-3732.

66. By virtue of the acts described above, Pfizer knowingly and willfully made, used or caused to be made or used, false records and statements, in order to get false or fraudulent claims paid or approved by the United States.

67. Plaintiff, United States, unaware of the falsity of the records, statements and/or claims made or used by Pfizer, or caused to be made or presented by Pfizer, and in reliance of

the accuracy thereof, approved and paid and/or reimbursed Pfizer with government funds, representing numerous violations of 31 U.S.C. §3729 (a)(2).

68. By reasons of the payments of these false and fraudulent claims, the United States has been damaged in substantial amounts.

COUNT THREE
False Claims Act, 31 U.S.C. §3729 (a)(3)

69. Relator realleges and incorporates by reference herein each and every allegation made above in paragraphs 1 through 68 of this Complaint in his claims for damages and forfeitures under the False Claims Act, 31 U.S.C. §§3729-3732.

70. By virtue of the acts described above, Pfizer knowingly and willfully conspired to defraud the United States by getting the United States to pay, either directly or indirectly, a claim for the purchase of Lyrica.

71. Plaintiff, United States, unaware of the promotional scheme adopted and implemented by Pfizer, and in reliance on the accuracy and regulatory compliance of Pfizer for the marketing of Lyrica, paid the false and fraudulent claims presented for the purchase of Lyrica, which constitutes numerous violations of 31 U.S.C. §3729(a)(3).

72. By reasons of these payments, the United States has been damaged in substantial amounts.

COUNT FOUR
Avoiding Federal Price Controls/
Experimental Use Of Drug

73. Relator realleges and incorporates by reference herein each and every allegation made above in paragraphs 1 through 72 as if fully set forth herein.

74. Federal law, in particular 21 C.F.R. §312.7, imposes price controls on investigational new drugs used in clinical trials. The regulations state that charging for an investigational new drug is not permitted without FDA approval.

75. Pfizer has launched a nationwide illegal program of experimentation with Lyrica. Although Pfizer has actually commenced certain legitimate clinical trials of Lyrica to control pain in limited circumstances, Pfizer has simultaneously encouraged and caused many physicians to experiment with Lyrica for off-label uses. These experimental programs are informal, generally unscientific, and not reported to the FDA. These information experiments have been conducted for the dual purpose of increasing sales of Lyrica while at the same time developing data for possible use with the FDA. These informal experiments were conducted by means of prescriptions to patients whose prescriptions have been paid for, in a substantial number of cases, by Medicare and Medicaid at regular prices.

76. Pfizer's deliberate avoidance of federal price controls on the experimental investigational use of drugs has caused financial harm to the federal government by inducing the federal government to pay for drug prescriptions for which payment is prohibited by federal law. Pfizer's deliberate avoidance of federal price controls on experimental use of drugs constitutes a pattern of fraudulent conduct which induced payments by the federal government, and constitute additional False Claims within the meaning of 31 U.S.C. §3729.

COUNT FIVE
Violating State Formularies/
Medicare And Medicaid

77. Relator realleges and incorporates by reference herein each and every allegation made above in paragraphs 1 through 76 as if fully set forth herein.

78. Under the statutes and regulations establishing the Medicare and Medicaid programs, the individual states are permitted to establish drug utilization review boards and formularies which define those prescription drugs and their uses for which a state agency will make reimbursement under their Medicare programs. Federal law, in particular 42 U.S.C. §1396r-8, requires a state formulary to include medically accepted uses of prescription drugs by reference to the publications set forth therein.

79. Many state Medicare agencies intend not to reimburse for prescription drugs for uses not set forth in their publications, in that the states do not intend to spend money on prescriptions not recognized as medically necessary in sources specified by federal law. However, many states lack the technical ability to monitor precisely for medical diagnoses in the case of individual prescriptions, and thus lack the technical ability to reject reimbursement for off-label uses of prescription drugs which are not medically accepted according to the federally specified publications. This lack of technical ability represents a loop-hole in the scheme of the Medicare and Medicaid programs.

80. Pfizer has recognized and aggressively exploited this loop-hole by means of a direct, illegal, nationwide program of promotion of off-label use of Pregabalin by physicians. Pfizer has conducted this program of promotion knowing that prescriptions for Pregabalin are generally reimbursed by the state Medicare programs even though individual prescriptions for Pregabalin fall outside of state formularies because they are not medically accepted.

81. Pfizer's aggressive, illegal scheme of off-label promotion has induced federal payments through a pattern of fraudulent conduct by causing the states, and thus the federal government, to pay out sums to claimants they did not intend to benefit. Pfizer's conduct constitutes additional acts of False Claims within the meaning of 31 U.S.C. §3729.

COUNT SIX
False Statements To Physicians

82. Relator realleges and incorporates by reference herein each and every allegation made above in paragraphs 1 through 81 as if fully set forth herein.

83. As part of its illegal off-label promotion of Lyrica, Pfizer has instructed and caused its sales personnel and its medical employees to make false statements to physicians, and to provide physicians with written materials containing false statements concerning the safety and efficacy of Lyrica. These statements were made with the intent of, and had the effect of, inducing physicians to increase the prescribing of Lyrica. This increased prescribing of Lyrica has cause and continues to cause harm to the federal government by increasing the number of Medicare claims for Lyrica prescriptions.

84. The false statements made by Pfizer employees to physicians have included representations that scientific evidence exists that Lyrica is a more effective remedy for certain conditions. The false statements also include representations that Lyrica is known to be safe and effective for the indications listed in the "off-label" list give to Relator as a marketing tool, and used by Pfizer in its marketing scheme. The false statements include representations that clinical trials are ongoing or planned with respect to each of the above off-label uses. Each of these statements is unsupported by any legitimate scientific evidence.

85. Pfizer's false statements made to physicians were a pattern of fraud designed to induce payments by the federal government, and constituted additional False Claims within the meaning of 31 U.S.C. §3729.

COUNT SEVEN
Avoiding Price Controls
Based On Therapeutic Equivalency

86. Relator realleges and incorporates by reference herein each and every allegation made above in paragraphs 1 through 85 as if fully set forth herein.

87. The federal laws establishing the Medicare and Medicaid programs contain drug price controls based on therapeutic equivalencies, as established by the FDA in an official publication (42 U.S.C. §1396r-8). Pfizer's illegal program of off-label promotion and avoidance of proper FDA procedures for approval of a new drug use has resulted in the lack of any classification of Pregabalin for therapeutic equivalency as to its off-label uses, such as pain control and control of bi-polar disorder. In fact, Pregabalin is relatively ineffective for chronic back pain control and bi-polar disorder. As a result, Pregabalin has not been subject to federal Medicare price limits based on therapeutic equivalency.

88. The federal government has been harmed by this avoidance of a rating of Pregabalin for therapeutic equivalency because other less expensive drugs are capable of conferring the same benefit as Pregabalin for various off-label uses. If Pregabalin were properly rated for therapeutic equivalency, the states and the federal government would be able to achieve the same benefits for less money.

89. Pfizer's illegal scheme of off-label promotion is a deliberate avoidance of federal price controls based on therapeutic equivalency, and constitutes inducement of federal payments through a pattern of fraudulent conduct and constitutes a additional False Claims within the meaning of 31 U.S.C. §3729.

COUNT EIGHT.
Retaliation, 31 U.S.C. §3730 (h)

90. Relator realleges and incorporates by reference herein each and every allegation made above in paragraphs 1 through 89 as if fully set forth herein.

91. By virtue of the acts described above and because Relator engaged in protected activity, Pfizer knowingly and willfully harassed, threatened and discriminated against Relator in the terms and conditions of his employment, including but not limited to his ultimate termination from employment.

92. Such threats, harassment, discrimination, and termination are in direct violation of the False Claims Act's protections.

93. By reasons of the acts described above, Relator has been damaged in substantial amounts.

COUNT NINE.
Wrongful Termination

94. Relator herein incorporates by reference all allegations previously set forth in this Complaint, the same as if set forth verbatim herein.

95. There is a clear public policy expressed in federal and state law that employees should not be terminated for reporting or opposing illegal conduct.

96. Pfizer's above-described actions violate this fundamental and well-defined public policy, and are willful, wanton and malicious in nature.

97. As a direct and proximate result of Pfizer's unlawful conduct, as described above, Relator has been damaged and is entitled to compensation from Pfizer therefore.

WHEREFORE, Relator respectfully requests that this Court enter judgment against Defendant Pfizer as follows:

(1) That the Defendant Pfizer cease and desist from violating 31 U.S.C. §3729.

(2) That this Court enter judgment against Defendant Pfizer in an amount equal to three times the amount of damages the United States Government has sustained because of the Defendant's actions, plus a civil penalty of not less than $5,000.00 and not more than $10,000.00 for each violation of 31 U.S.C. §3729;

(3) That Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act;

(4) That Relator be awarded all compensatory and punitive damages with respect to statutory and tort claims in an amount being just;

(5) That Relator be awarded all costs of this action, including attorney's fees and court costs; and

(6) That Relator recover such other relief as the Court deems just and proper.

Respectfully submitted,

B. DAHLENBURG BONAR, P.S.C.

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REQUEST FOR TRIAL BY JURY

Relator hereby requests a trial by jury.

ANTHONY J. BUCHER (#87126)